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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,909	01/10/2006	Marco Pirovano	4017-41	5626
23117 7590 01/07/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/563,909

Applicant(s)

PIROVANO ET AL.

Examiner

Bhisma Mehta

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,40,41,43,45-48,50-52 and 54-74 is/are pending in the application.
- 4a) Of the above claim(s) 60-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,40,41,43,45-48,50-52 and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/22/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on October 22 2007. These drawings are acceptable.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the system with a container arrangement and a pumping device where the pumping device is an elastomeric container must be shown or the feature(s) canceled from the claim(s). Also, the command and control device must be shown or the feature(s) canceled from the claim(s). In response to Applicant's indication on page 10 of the Remarks filed October 22 2007 that the command and control device corresponds to element 19, it is suggested that the specification be amended at line 22 of page 6 to indicate that the command and control device is also called the piloting device. This would then overcome the objection that the command and control device is not shown in the drawings. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 45-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The distinction between the container arrangement of claim 38 and the elastomeric container of the pumping device of claim 45 is unclear. Specifically, it is unclear how the system of the container arrangement and the pumping device can be further defined by the pumping device comprising an elastomeric container since Applicant has indicated on page 10 of the Remarks filed October 22 2007 that the container arrangement corresponds to element 3 in Figure 1 which is defined as the elastomeric container in lines 4-5 of page 5 of the specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 38, 40, 41, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Corbin et al (U.S. Patent No. 3,252,623). Corbin et al disclose an infusion system having a container arrangement (10), a pumping device (14), an adjusting device (24), and a command and control device (45). The adjusting device comprises a valve arrangement in the form of a solenoid valve which is normally closed. The command and control device operates the valve arrangement to command a pulsed actuation of the valve arrangement (see lines 16-26 and lines 51-60 of column 3). The command and control device is provided with an electric supply apparatus which is connected to the command and control device by a channel (35).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 43 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al in view of Franetzki et al (U.S. Patent No. 4,270,532). Corbin et al

disclose the system substantially as claimed. However, Corbin et al are silent on the specifics of the command and control device comprising a microprocessor, an interface element, or a reading device. Franetzki et al disclose an infusion system having a container, a pumping device, and a command and control device comprising a microprocessor (I). The command and control device also has an interface element for operationally connecting the command and control device to a data processing system (44) and a reading device for receiving a data recording support in the form of a smart-card type (lines 38-52 of column 2 and lines 3-24 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the command and control device of Corbin et al with a microprocessor or an interface element as taught by Franetzki et al as Franetzki et al disclose that it is well known to use a command and control device having a microprocessor or an interface element to allow the desired infusion to be pre-programmed and monitored by a physician. To provide the command and control device of Corbin et al with a reading device as taught by Franetzki et al would have also been obvious to one having ordinary skill in the art at the time the invention was made as Franetzki et al disclose that it is well known to use a command and control device having a reading device to allow for the programming data which is already stored on a carrier or card to be easily read by the command and control device.

9. Claims 45-48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al in view of Kanai et al (U.S. Patent No. 6,367,502). Corbin et al disclose the system substantially as claimed. However, Corbin et al are

silent on the pumping device comprising an elastomeric container. Kanai et al disclose an infusion system having a container arrangement and a pumping device comprising an elastomeric container (11) which is supported on a support element (10) associated with a transparent containing and protection element (2). The containing and protection element has a scale (4). The containing and protection element has an inlet portion (19) with a check valve (13) and a connecting element (17) and an outlet portion (18) which is connected to a first end of a fitting element (30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the pumping device of Corbin et al with the pumping device having an elastomeric container as taught by Kanai et al as both Corbin et al and Kanai et al disclose infusion systems having a pumping device and the pumping device of Kanai et al could be used in the infusion system of Corbin et al as an equivalent way of generating a flow of solution.

10. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al in view of Crankshaw et al (U.S. Patent No. 4,741,732). Corbin et al disclose the system substantially as claimed. However, Corbin et al are silent on the electrical supply apparatus being a battery. Crankshaw et al disclose an infusion system with a command and control device (120) having a rechargeable battery (129). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the electrical supply apparatus of Corbin et al with the rechargeable battery as taught by Crankshaw et al as Crankshaw et al teach that it is well known to use rechargeable batteries to provide the power needed to operate a command and control device in an infusion system.

Response to Arguments

11. Applicant's arguments filed October 22 2007 have been fully considered but they are not persuasive. The system of Corbin et al does have a pumping device (14). Applicant's argument that "a pumping device is generally defined as a device that moves liquids from lower pressure to higher pressure overcoming the difference in pressure by adding energy to the liquid" and, thus the system of Corbin et al does not comprise a pumping device, is not deemed persuasive. The feature of the system of Corbin et al indicated by reference character 14 can be considered to be a pumping device as it is an apparatus that forces or draws a liquid from or to another part of the system where gravity is what allows the liquid to be moved. Also, the pumping device (14) does generate a flow of the solution from the container arrangement to the catheter.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

